CLAIMS

What is claimed:

1. A device for determining the quality of reagents used in an assay, comprising:

a) a plurality of quality control compounds, wherein each said compound is reactive with a different reagent used in said assay; and

b) a substrate, wherein each said control compound is bound on a plurality of spatially defined sites on said substrate, and wherein each said defined site contains a different amount of said control compound.

2. The device of claim 1, wherein said substrate comprises a solid substrate.

3. The device of claim 1, wherein said solid substrate comprises plastic, glass, quartz, or silicon.

4. The device of claim 3, wherein said glass comprises a microscope slide.

5. The device of claim 1, wherein said different amount is a serial dilution series of said control compound.

6. The device of claim 1, wherein at least one of said quality control compounds consists essentially of a compound reactive with said reagent, where in said reagent is a secondary reagent.

7. The device of claim 1, wherein said plurality of quality control compounds comprise at least one ligand, wherein at least one of said reagents is a binding partner of said ligand.

8. The device of claim 7, wherein said ligand comprises a hapten.

9. The device of claim 7, wherein said ligand comprises biotin.

10. The device of claim 7, wherein said ligand comprises an epitope bound by a reagent antibody.

11. The device of claim 10, wherein said antibody comprises a non-primary antibody.

12. The device of claim 10, wherein said epitope comprises a protein.

13. The device of claim 12, wherein said protein comprises serum protein.

14. The device of claim 13, wherein said serum protein is selected from the group consisting of serum protein from bovine, cat, chicken, dog, donkey, goat, guinea pig, hamster, horse, human, mouse, rabbit, rat, sheep, and swine.

15. The device of claim 12, wherein said protein is selected from the group consisting of immunoglobulin isotypes IgG, IgM, IgA, and IgE.

16. The device of claim 1, wherein at least one of said quality control compounds comprise at least one detection enzyme.

17. The device of claim 16, wherein said detection enzyme is selected from the group consisting of β-galactosidase, horseradish peroxidase, alkaline phosphatase, glucose oxidase, β-glucouronidase, urease, glucose-6-phosphate dehydrogenase, and lactate dehydrogenase.

18. The device of claim 1, wherein said control compound comprises a histochemical stain control compound.

19. The device of claim 18, wherein said histochemical stain control compound reacts with a dye selected from the group consisting of hematoxylin, methyl green, methylene blue, pyronine, and toluidine blue, acid fuchsine, aniline blue, eosin, and orange G.

20. The device of claim 1, wherein said device contains an identifying code.

21. The device of claim 1, wherein said plurality of quality control compounds comprise serum proteins, ligands, haptens, and detection enzymes.

22. The device of claim 1, wherein said assay comprises an immuno-based assay.

23. The device of claim 1, wherein said assay comprises an immunohistochemical assay.

24. The device of claim 1, wherein said assay comprises an hybridization assay.

25. A method of determining the quality of reagents used in an assay process, comprising:

a) contacting a plurality of different reagents with a substrate comprising a plurality of quality control compounds, wherein each said control compound is reactive with at least one of said reagents used in said assay, wherein said control compound is bound to said substrate on a plurality of spatially defined sites, each said defined site containing a different amount of said control compound;

b) assessing the extent of reaction of at least one of said reagents with said compound on said plurality of spatially defined sites.

26. The method of claim 25, wherein said substrate comprises a solid substrate.

27. The method of claim 25, wherein said substrate is plastic, glass, quartz, or silicon.

28. The method of claim 25, wherein said solid substrate comprises a microscope slide.

29. The method of claim 25, wherein said different amount is a serial dilution series of said compound.

30. The method of claim 25, wherein at least one of said quality control compounds consists essentially of a compound reactive with said reagent, where in said reagent is a secondary reagent.

31. The method of claim 25, wherein said plurality of quality control compounds comprise at least one ligand and said reagent comprises a binding partner of said ligand.

32. The method of claim 31, wherein said reagent comprises an antibody and said ligand comprises an epitope bound by said antibody.

33. The method of claim 32, wherein said epitope comprises serum protein bound by said antibody.

34. The method of claim 31, wherein said ligand comprises biotin and said reagent comprises avidin.

35. The method of claim 25, wherein said plurality of quality control compounds comprise at least one detection enzyme and said reagent comprises a substrate for said enzyme.

36. The method of claim 25, wherein said plurality of quality control compounds comprise at least one histochemical stain control compound.

37. The method of claim 25, wherein said assessing is by measuring a detectable signal.

38. The method of claim 25, wherein said assay process comprises an immune-based assay.

39. The method of claim 25, wherein said assay comprises an immunohistochemical assay.

40. The method of assessing the performance of an assay, said method comprising:

a) providing a substrate comprising a plurality of quality control compounds, wherein each said control compound is reactive with a different reagent used in an assay process used to detect an analyte, wherein said compound is bound to said substrate on a plurality of spatially defined sites, each said defined site containing a different amount of said quality control compound;

b) performing at least one step of said assay on said substrate, wherein said substrate is contacted with at least one of said reagents; and

c) assessing the reaction of said quality control compound and said reagent.

41. The method of claim 40, wherein said assay is performed simultaneously on said device and a biological sample being assayed.

42. The method of claim 40, wherein first and second assays are performed and said method further comprises comparing said reaction in said first and second assay, whereby the performance of said first and second assay are determined.

43. A method of assessing the quality of reagents used in an assay, said method comprising:

a) providing a substrate comprising a plurality of quality control compounds, wherein

each said compound is reactive with a different reagent used in said assay, wherein said compound is bound to said substrate on a plurality of spatially defined sites, each said defined site containing a different amount of said quality control compound;

b) performing said assay on a first said substrate with a first set of assay reagents comprising control reagents;

d) performing said assay on a second said substrate with a second set of assay reagents comprising test reagents; and

c) detecting the reaction of said control and test reagents.

44. The method of claim 43, further comprising step d) comparing said reaction of said control and test reagents.

45. The method of claim 44, wherein said control reagents and said test reagents comprises assay reagents stored for different time periods

46. The method of claim 44, wherein said control reagents and said test reagents comprise different preparations of said assay reagents.